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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,907	06/15/2001	Harold G. Brown	2059-0106P	7324

2292 7590 10/07/2002

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EXAMINER

KHARE, DEVESH

ART UNIT PAPER NUMBER

1623

DATE MAILED: 10/07/2002

10

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/880,907

Applicant(s)

BROWN ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 August 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Art Unit: 1623

The applicants' response, copies of declarations under 37 CFR 1.131 and 1.132 received on 08/08/2002 have been entered. The applicant's response on the rejection of claims 1-26 under 35 U.S.C. 102(e) anticipated by either Mausner (U.S. Patent 5,215,759) or Tayler-McCord (U.S. Patent 5,266,318) is acknowledged. The rejection of claims 1-26 under 35 U.S.C. 102(e) anticipated by either Mausner (U.S. Patent 5,215,759) or Tayler-McCord (U.S. Patent 5,266,318) is withdrawn.

It is acknowledged that the present application was filed as a Rule 53(b) application on June 15, 2001, thus American Inventors Protection Act of 1999 (AIPA) does appear to apply. Claims 1-26 are currently pending in this application.

35 U.S.C. 103(a) rejection

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lowry (U.S. Patent 4,900,550) in view of Williams et al. (*Int. J. Pharm*, vol. 57: R7-R9).

The applicant's claims are broadly directed toward affecting transdermal migration of a compound by mixing the compound with an essential oil. Claim 2 place further limitations as to the nature of the compound (i.e., a complex carbohydrate).

Further limitations in the applicant's claims include specific ranges for the amount of essential oil (from 0.5% to 20% vol/vol, claim 4), degree of purity of the complex

Art Unit: 1623

carbohydrate (concentration ranging 0.1% to 99%, claim 21), and scope of the complex carbohydrates and essential oils used.

Lowry teaches the use of several different types of macromolecules and complex carbohydrates in combination with essential oils, which is readable upon the scope of the applicant's claims. The compositions disclosed by Lowry include the hyaluronic acid in an amount of 0.09-0.11 wt.% (col. 4, line 13) and sweet almond oil in an amount of 0.09-0.11 wt.% (col. 3, line 67).

Lowry differ from the applicants invention primarily in the scope of complex carbohydrates/essential oils used, the Lowry composition contains hyaluronic acid below 0.3 wt.% and essential oil below 2% vol/vol. However, as Williams et al. disclose, it was well known at the time the invention was made that essential oils were useful as skin penetration enhancers and a wide variety of compounds could be used with essential oils for transdermal penetration (summary and Table 1).

Therefore, when taking the invention as a whole, the use of an essential oil with a macromolecule/complex carbohydrate would have been obvious to one of ordinary skill in the art. Since Lowry teaches the use of several different types of macromolecules and complex carbohydrates in combination with essential oils and Williams et al. teach that the essential oils were useful as skin penetration enhancers and a wide variety of compounds could be used with essential oils for transdermal penetration, one skilled in the art would have a reasonable expectation for success in combining both references

Art Unit: 1623

to accomplish a therapeutic composition comprising combining the essential oils useful as skin penetration enhancers and a wide variety of compounds for transdermal penetration.

35 U.S.C. 102(e) rejection

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 1 -26 are rejected under 35 U.S.C. 102(e) as being anticipated by Lowry (U.S. Patent 4,900,550).

Lowry discloses the use of several different types of macromolecules and complex carbohydrates in combination with essential oils, which is readable upon the scope of the applicants claims.

Response to Applicant's Arguments

Examiner has carefully reviewed the prosecution history and the applicant's arguments filed on 08/08/02 but they are not persuasive.

Applicants appear to be arguing against Lowry that the Lowry reference does not anticipate or suggest the present invention because the active ingredients is not present in a pharmaceutically effective amount. This is not found to be persuasive because:

(1) The declaration under 37 CFR 1.132 shows that when hyaluronic acid is used at a concentration below 0.3 wt% when combined with 2% vol/vol tea tree oil, the composition will not have pain relieving effect. The applicants argue that the lower amount of hyaluronic acid (0.09-0.11 wt.%) and essential oil (0.09-0.11 wt.%) of the Lowry reference would be pharmaceutically ineffective and thus not fall within the scope of the present invention however applicants are claiming the same lower amounts of hyaluronic acid and essential oils as a pharmaceutically effective amount in claims 4-9 and 21-24.

(2) There is no limitation in the claims 1,3 and 11 language, which requires that the composition be a pharmaceutical effective composition as supported in the declaration under 37 CFR 1.132.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is (703)605-1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

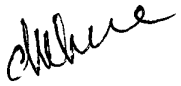
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be

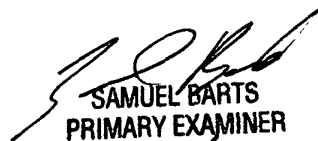
Application/Control Number: 09/880,907
Art Unit: 1623

Page 6

reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.


Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
October 4,2002


SAMUEL BARTS
PRIMARY EXAMINER
GROUP 1000